

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 5/19/2025-5/22/2025 FEI NUMBER 3009542936	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brian K. Schwarz, President and Chief Technology Officer			
FIRM NAME Lattice Inc		STREET ADDRESS 1751 S Naperville Rd Ste 100	
CITY, STATE, ZIP CODE, COUNTRY Wheaton, IL 60189-5896		TYPE ESTABLISHMENT INSPECTED Software Manufacturer	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above. <i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>			
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Risk analysis is inadequate and is incomplete. Specifically, 1. Your firm failed to complete risk analysis for your class II medical device, MediCopia Transfusion, for version (b) (4) (Manufacture release date (b) (4)), (b) (4) (Manufacture release date (b) (4)), and (b) (4) (Manufacture release date (b) (4)). New risks were identified during design validation of the aforementioned version releases; however, no analysis of the newly identified risks were documented. 2. Your firm's risk analysis document "MediCopia Transfusion Hazard Analysis" revision 1.2, updated 08/19/2011, is inadequate. This risk analysis does not evaluate risk control specific to eliminating or mitigating risk levels to an acceptable value. This risk analysis was utilized for version (b) (4) (Manufacture release date (b) (4)), (b) (4) (Manufacture release date (b) (4)), and (b) (4) (Manufacture release date (b) (4)). 3. Your firm's procedure, SOP300 "Risk/Hazard Analysis" revision 01, effective 4/24/2005, and revision 02, effective 01/07/2022, does not define risk control specific to eliminating or			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Lesley Mae P Lutao, Investigator Zoey A Trombley, Investigator Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - B Date Signed: 05-22-2025 13:02:54 	
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mitigating risk levels to an acceptable value.

MediCopia Transfusion version (b) (4) to (b) (4) has been released to (b) (4) customers, (b) (4) of which are currently active on version (b) (4) and version (b) (4)

OBSERVATION 2

Procedures for corrective and preventive action have not been established.

Specifically,

Your firm's procedure, SOP401 "Corrective and Preventative Action" revision 04, effective January 1, 2020, does not include all requirements, for example:

1. The procedure does not define appropriate statistical methods employed to detect recurring quality problems.
2. The procedure does not include verification or validation of the corrective action to ensure the implemented corrective and preventive actions adversely affected the finished device.
3. In two (2) of three (3) CAPA records reviewed, there was no assessment to determine whether the implemented corrective and preventive actions adversely affected the finished device.

This was a repeat observation from the inspections conducted on 1/6-17/2020 and 11/19/2012-12/06/2012.

OBSERVATION 3

Procedures for quality audits have not been adequately established.

Specifically,

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Your firm's only procedure that defines quality audits, "Lattice Quality Manual" revision 1.3, effective 4/15/2020, does not specify how quality audits are performed to cover all elements of the quality system, and does not require quality auditors to have the necessary background, training, or experience to assure quality audits are performed adequately. For example: 1. Deficiencies were found in your quality systems: Design Controls (see OBSERVATION 1), Corrective and Preventive Action (see OBSERVATION 2), Document Controls (see OBSERVATION 4), Purchasing Controls (see OBSERVATION 7). 2. Your firm performed quality audits from 2021 to 2024 utilizing a document titled "CONSULTING MEMORANDUM – QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CHECKLIST" that does not include all elements in the quality system. On 05/21/2025, your quality auditor stated they perform quality audits using only this checklist. In addition, this checklist has not been reviewed and approved (see OBSERVATION 4). 3. Your training records "Lattice Training Matrix" does not identify quality auditor training requirements. This was a repeat observation from the inspection conducted on 11/19/2012-12/06/2012. OBSERVATION 4 Documents were not reviewed and not approved by designated individual(s) prior to issuance . Specifically, 1. Your firm performed management reviews utilizing the document titled "Lattice MediCopia 202X Annual Management Review Record" that has not been reviewed and approved for use. This record was used to document (b) (4) management reviews from 2021 to 2024.			
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2. Your firm performed quality audits utilizing the document titled “CONSULTING MEMORANDUM – QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CHECKLIST” that has not been reviewed and approved. This record was used to document (b) (4) quality audits from 2021 to 2024.			
OBSERVATION 5 The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830. Specifically, Your firm’s class I medical device, MediCopia and class II medical device, MediCopia Transfusion does not bear a unique device identifier (UDI) in the labeling. For example: 1. There has been no submission of device identification data to the Global Unique Device Identification Database (GUDID). 2. Device history records for MediCopia Transfusion version (b) (4) (Manufacture release date (b) (4)) to version (b) (4) (Manufacture release date (b) (4)) does not include any UDI. 3. Since the previous inspection, there have been twenty-three (23) complaints related to your class II medical device, MediCopia Transfusion. Of the thirteen (13) complaint records reviewed, none included any UDI. MediCopia Transfusion version (b) (4) has been released to (b) (4) customers since the last inspection, (b) (4) of which are currently active on version (b) (4) and version (b) (4)			
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TYPE ESTABLISHMENT INSPECTED _____

Software Manufacturer

Procedures to control labeling activities have not been established.

Specifically,

Your firm has not established and maintained procedures to control labeling activities of your firm's class II medical device, MediCopia Transfusion.

This was a repeat observation from the inspection conducted on 11/19/2012-12/06/2012.

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically,

1. Your firm has not performed an evaluation of suppliers, contractors, and consultants when your firm purchases off-the-shelf hardware, contracts the maintenance of back-up servers, and consults quality assurance activities for (b) (4) platforms.
2. Your firm has not established and maintained procedures to ensure that all purchased or otherwise received product and services conform to your requirements, including quality requirements.

This was a repeat observation from the inspection conducted on 11/19/2012-12/06/2012.

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Zoey A Trombley, Investigator

Lesley Mae P. Lutaso
Investigator
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X Zoey A Trombley
Investigator
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Annotations to Observations Observation 1: Promised to correct Observation 2: Promised to correct Observation 3: Promised to correct Observation 4: Promised to correct Observation 5: Promised to correct Observation 6: Promised to correct Observation 7: Promised to correct			
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 7 of 7 PAGES			

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."